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Questions for EPA:

Questions for EPA on PFAS:

Below is the information posted on EPA's webpage for PFAS in Pesticide Packaging ([HYPERLINK "https://www.epa.gov/pesticides/pfas-packaging"]; Accessed on August 31, 2021).

SFIREG-EQI/POM working committees would appreciate to learn of updates on various aspects of the PFAS in pesticides issue. Inserted are questions for updates on various questions that were initially submitted to EPA earlier this year. The questions are inserted and highlighted in italics and underlined font.

Frequently Asked Questions

1. What is the definition of a PFAS compound in the context of pesticides?

Pesticides undergo a rigorous scientific assessment process prior to registration. EPA independently evaluates chemical-specific data to ensure that pesticides can be used safely and without unreasonable adverse effects to the environment when label directions are followed. In response to public interest in PFAS chemicals, the EPA Office of Pesticide Programs previously determined that there were no pesticide active or inert ingredients with structures similar to prominent PFAS such as PFOS, PFOA, and GenX. As further due diligence, we are now working with other offices in EPA (including the Office of Research and Development) to further evaluate structures by applying the latest working definition from our sister office, the Office of Pollution Prevention and Toxics (OPPT), which manages the Toxic Substances Control Act (TSCA) program.

OPPT applies the following "working definition" when identifying PFAS on the TSCA Inventory: a structure that contains the unit R-CF2-CF(R')(R"), where R, R', and R" do not equal "H" and the carboncarbon bond is saturated (note: branching, heteroatoms, and cyclic structures are included). Under FIFRA Section 6(a)(2), pesticide registrants should report to EPA additional factual information on unreasonable adverse effects, including metabolites, degradates, and impurities (such as PFAS). EPA considers any level of PFAS to be potentially toxicologically significant and may trigger 159.179(b) in the Code of Federal Regulations (CFR).

- **Question**: There appear to be a few registered active ingredients that meet the working definition, such as pyrifluquinazon and broflanilide. How does EPA address this situation given the information above?
- RD & Jeff Question. Maybe send to Cathryn Aubee

2. Why are HDPE containers fluorinated?

Information EPA currently has on fluorinated HDPE containers indicates that they are treated inside and outside through fluorination, a process that creates a chemical barrier for a pre-produced container to

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prevent changes in chemical composition. Using fluorous sealed technology improves container stability, and is intended to make containers less permeable, reactive and dissolvable.

3. What PFAS compounds were detected on or in the containers?

To date, testing on a limited number of fluorinated HDPE containers used by one pesticide product supplier show presence of the following PFAS compounds. Testing was performed by rinsing both the interior and exterior (when appropriate) of the container with methanol and analyzing the rinsates using a method modified from the [HYPERLINK

"https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=343042&Lab=NERL"].

Abbreviated name	Full name
PFBA	Perfluoro-butanoic acid
PFPeA	Perfluoro-pentanoic acid
PFHxA	Perfluoro-hexanoic acid
PFHpA	Perfluoro-heptanoic acid
PFOA	Perfluoro-octanoic acid
PFNA	Perfluoro-nananoic acid
PFDA	Perfluoro-decanoic acid
PFUdA	Perfluoro-undecanoic acid

Question: Is information in the FDA letter ([HYPERLINK

"https://www.fda.gov/media/151326/download?utm_medium=email&utm_source=govdelivery"]) considered in the context of these results? Not sure what this means—letter followed our posting of these results. We're aware of the letter. Has EPA taken note of the information on different methods of fluorination of HDPE containers? Certain methods include conditions where PFAS compounds are not formed as part of the fluorination process. We are aware that different fluorination methods/processes would affect whether or not PFAS is formed.

4. In what amounts were PFAS detected?

Results from testing samples of fluorinated and non-fluorinated HDPE containers, both unused and containing a mosquito control pesticide product, were found to contain varying levels of PFAS. After completing a robust quality assurance and quality control process, EPA can confirm that it has detected eight different PFAS from the fluorinated HDPE containers, with levels ranging from 20-50 parts per billion. [HYPERLINK "https://www.epa.gov/pesticides/rinses-selected-fluorinated-and-non-fluorinated-hdpe-containers"].

- Question: Can EPA provide an update on the container rinsate testing?
 - Thuy and Yaorong can provide an update on leaching testing. Thuy is out on the 20th, but
 Yaorong can cover.

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5. What do we know about these PFAS chemicals?

EPA researchers are working to understand how exposure to PFAS may be harmful to people and to the environment. These studies allow the agency to better understand how harmful specific chemicals can be and help prioritize the agency's work to protect public health. To learn more about the concrete steps the Agency is taking to address PFAS and to protect public health, please read [HYPERLINK "https://www.epa.gov/pfas/epas-pfas-action-plan"].

EPA continues to compile and assess human and ecological toxicity information on PFAS to support risk management decisions. EPA continues to work on toxicity assessments for GenX chemicals and PFBS. EPA is also developing toxicity assessments through its Integrated Risk Information System (IRIS) Program for PFBA, PFHxA, PFHxS, PFNA, and PFDA. Draft IRIS assessments are expected in 2021, more information is available at [HYPERLINK "https://www.epa.gov/iris/iris-program-outlook"] EPA is applying high-throughput toxicology testing to study the toxicity of the larger universe of PFAS. Laboratory and epidemiological studies on PFOA have shown the potential for adverse effects, such as developmental, thyroid, liver, and immune system effects and cancer.

• Question: Does EPA have updates on this effort? Jeff? I don' tthink we have must more to share, but Jeff will know.

6. Do we know to what degree long term storage or hot/cold storage conditions might affect the concentration of PFAS leaching?

EPA anticipates the length of time and the conditions under which the product was stored in fluorinated containers could affect the actual concentration of PFAS found in the product itself. EPA is planning to conduct a study to determine under what conditions, generally, PFAS compounds will leach from container walls into the pesticide products.

Question: Does EPA have updates on this effort? Yaorong – update on leaching testing.

7. What consideration, if any, is being given to pesticide container recycling programs in regard to the fluorinated HDPE containers?

EPA has been in contact with the Ag Container Recycling Council. As more information becomes available, EPA will continue to work in collaboration with other federal entities to provide guidance to states and localities that may be affected by PFAS.

• Question: Does EPA have updates on this effort? Jeff — OPPT? Who handles recycling? No updates that I'm aware of.

8. Should people be concerned about the possibility of being exposed to PFAS from pesticide container contamination? What about other containers?

The PFAS detections in rinsate from the tested containers do not represent PFAS concentrations in the environment or human exposure to PFAS. While EPA is early in its investigation, the agency will use all

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available regulatory and non-regulatory tools to determine the scope of this emerging issue and its potential impact on human health and the environment.

Question: Does EPA have updates on this effort? See Q.5 EPA researchers are working to
understand how exposure to PFAS may be harmful to people and to the environment. These
studies allow the agency to better understand how harmful specific chemicals can be and help
prioritize the agency's work to protect public health.

9. When did EPA first learn of this contamination? What steps have been taken since initial PFAS discovery in the pesticide product?

On September 1, 2020, Public Employees for Environmental Responsibility (PEER) contacted the Massachusetts Reclamation Board, the Massachusetts Department of Agricultural Resources' (MDAR) Division of Pest Services, and other state agencies claiming that there were unspecified PFAS in a pesticide used for mosquito control. EPA Region 1 was notified that same day.

Since being notified, EPA has worked diligently in conjunction with the Massachusetts Department of Environmental Protection (MassDEP) to request samples of the pesticide product and analyze the identified product at different steps of production and manufacturing to determine whether PFAS are present, including issuing an information request to the pesticide registrant on October 5, 2020, seeking information on the affected pesticide's production, sales and distribution.

In December 2020, rinsates of used and unused fluorinated HDPE containers used to store and transport the pesticide product yielded results supporting that the source of contamination is associated with the fluorinated HDPE containers. EPA has been in close contact with MDAR, the pesticide registrant and the fluorinated HDPE container treatment company to discuss the issue, as well as to obtain the materials needed to test for PFAS in the product and the fluorinated HDPE containers.

On January 13, 2021, to minimize risks to human health and the environment, EPA asked states with existing stock of the mosquito product distributed in fluorinated HDPE containers to discontinue use and hold until its final disposition is determined. The pesticide manufacturer has notified all its customers regarding management of the product, voluntarily stopped shipments of all products in fluorinated HDPE containers and is now using non-fluorinated containers.

On January 14, 2021, EPA issued a TSCA subpoena to the company that fluorinates the containers supplied to the manufacturer of the pesticide in which PFAS was discovered to learn more about the fluorination process used on the HDPE containers.

Question: Does EPA have updates on this effort? OPPT – TSCA Subpoena update?

EPA is aware that many companies are using fluorinated HDPE containers to store and distribute pesticide and other products. EPA is actively working with the Food and Drug Administration, the U.S. Department of Agriculture, and industry and trade organizations to raise awareness of this emerging issue and discuss expectations of product stewardship. For example, EPA is coordinating with the Ag Container Recycling Council, the American Chemistry Council, Crop Life America, the Household & Commercial Products Association, and the National Pest Management Association.

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 Question: Does EPA have updates on this effort? EPA is committed to sharing information out of the BEAD lab as it becomes available; encourage direct conversation with FDA & manufacturers.
 We have raised awareness of the issue; understand that some companies have taken proactive efforts to address the situation for their individual products.

The agency is also testing different brands of fluorinated containers to determine whether they contain and/or leach PFAS, and if so, learn the conditions affecting leaching. *EPA will present these findings as expeditiously as possible.*

Question: Does EPA have updates on this effort? Yaorong & leaching studies – see above.

The agency is encouraging the pesticide industry to explore alternative packaging options, like steel drums or non-fluorinated HDPE.

• Question: Does EPA have updates on this effort? We have raised awareness of the issue; understand that some companies have taken proactive efforts to address the situation for their individual products.

10. What containers are being purchased off the open market for additional testing by EPA and are they the same level of fluorination as the initial container rinsate testing? If not, is there a reason similar containers are not being used to perform the leaching studies?

EPA has obtained fluorinated containers from different manufacturers and vendors from open market. We are exploring numerous brands of containers by different manufacturers and from different vendors which may be fluorinated by various fluorination operators. Some of the containers from several vendors are still back-ordered.

The lab is not testing similar containers as those used initially in the rinsate testing because it is unknown which containers are fluorinated by the same company as the containers that were initially tested.

• Question: Does EPA have updates on this effort? Yaorong & leaching studies – see above.

11. What should pesticide registrants do if they find PFAS in their production lines?

Under [HYPERLINK "https://www.epa.gov/pesticide-incidents/incident-reporting-pesticide-manufacturers-registrants"], pesticide registrants should report to EPA additional factual information on unreasonable adverse effects, including metabolites, degradates, and impurities (such as PFAS). EPA considers any level of PFAS to be potentially toxicologically significant and may trigger 159.179(b) in the Code of Federal Regulations (CFR). Under [HYPERLINK "https://www.ecfr.gov/cgi-bin/text-idx?SID=680dff323249c84b0f88ddd044793a71&mc=true&node=pt40.24.159&rgn=div5"], 6(a)(2)

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information about impurities must be received by EPA no later than the 30th calendar day after the registrant first possesses or knows of the information.

In a shared interest to remove PFAS from the environment, if companies find PFAS in their product, they should notify EPA and take action to remove contaminated product. If product packaging is suspected as a source and you are considering replacing the packaging, please consult with EPA on data to be submitted for review prior to distribution of the pesticide product with the alternative packaging.

Question: Has EPA received notifications in the context the information above? I don' tthink we
can comment on any action specifically, but we have raised awareness of the issue; understand
that some companies have taken proactive efforts to address the situation for their individual
products.

•

12. How is EPA coordinating with other federal partners to address this issue?

EPA is in close communication with the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) to understand the extent and significance of the PFAS contamination. As more information becomes available, EPA will continue to work in collaboration with other federal entities to provide guidance to states and localities that may be affected by PFAS.

- Question: Does EPA have updates on this effort? EPA is committed to sharing information out of the BEAD lab as it becomes available; encourage direct conversation with FDA
- 13. EPA has indicated a "clean up" of PFAS in the Pesticide Inert Finder database as the database includes some PFAS compounds. EPA further indicated that even though these compounds were listed, they do not occur in currently registered pesticide products. Could an update be given on the effort to clean up the inert database?

EPA continues to update its public-facing InertFinder database to remove legacy entries for chemicals that are not currently in use.

- Question: Does EPA have updates on this effort? RD
- 14. Does EPA allow pesticide manufacturers to include PFAS in their formulations as inert ingredients which do not have to be reported?

No, EPA requires all inert ingredients in pesticide formulations to be reported as part of the Confidential Statement of Formula.

15. Do the data requirements for containers require information about fluorination to be submitted if containers are fluorinated?

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Yes, EPA's storage and stability/corrosion characteristics data requirements require registrants to provide details on the type of container used to distribute the product commercially, which can include fluorinated High-Density Polyethylene (HDPE) containers.

Question: Is the information in the FDA letter ([HYPERLINK "https://www.fda.gov/media/151326/download?utm_medium=email&utm_source=govdelivery "]) being considered with these data requirements? RD?

16. Do existing FIFRA container regulations address the use of fluorinated HDPE containers?

FIFRA pesticide container regulations do not specifically address the fluorination of plastic containers, i.e., the regulations do not require fluorination nor do they prohibit fluorination of plastic pesticide containers. However, some of the Department of Transportation requirements that are referred to and adopted in the pesticide container regulations may impact a pesticide manufacturer's decision to fluorinate containers. Discussions with the regulated industry are needed to better understand the impact of certain container requirements on a company's determination about whether fluorinated containers are needed.

• Question: Does EPA have updates on this effort? We have had some conversations with the regulated industry and have a better understanding of their container needs. That said, we continue to say that if PFAS is present (see question 11)

17. How will EPA keep the public informed as more information becomes available?

Along with keeping close communication with federal entities, states and localities, EPA will post updates on this webpage as the issue evolves. For any stakeholder questions regarding this issue not covered in this FAQ, you are welcome to contact EPA at [HYPERLINK

"mailto:pesticidepackaging@epa.gov"]. For any media inquiries, please email [HYPERLINK "mailto:press@epa.gov"].

Information for States

1. What advice should states and local mosquito control districts follow for making their purchasing decisions now?

States and local mosquito control districts are encouraged to contact their pesticide suppliers if there are questions about potential for PFAS in pesticide products they have purchased or intend to purchase. As the issue evolves, EPA will continue to communicate its findings to the states.

Question: Does EPA have updates on this effort? Actively collaborating with Maryland to test
mosquito products; hopefully by the 20thh we'll be able to share our final report with Maryland.
Collaborating/coordinating on any public messaging around this. If other states need assistance,
let us know.

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2. What are the alternatives to Anvil 10+10 for mosquito spray, and are the alternative pesticide products stored the same way?

Anvil 10+10 is one of many adulticides registered for use in public health mosquito control programs. Mosquitos pose a significant public health threat and can transmit serious diseases and viruses such as malaria, dengue virus, Zika and West Nile virus, which can lead to disabling and potentially deadly effects (such as encephalitis, meningitis and microcephaly). EPA and the Centers for Disease Control and Prevention (CDC) work closely with each other and with other federal, state, and local agencies to protect the public from mosquito-borne diseases. [HYPERLINK "https://www.epa.gov/mosquitocontrol"].

Fluorinated polyethylene and HDPE are used for numerous applications such as food packaging and containers for chemical storage, including pesticides. This is the first time that EPA has been aware of flourinated HDPE container use as a potential source of PFAS contamination in a pesticide. EPA is using its authorities under FIFRA and TSCA to obtain more information about the potential scope of this contamination and to evaluate whether other regulated products may be affected.

- Question: Is the information in the FDA letter ([HYPERLINK "https://www.fda.gov/media/151326/download?utm_medium=email&utm_source=govdelivery "]) being considered in this context?
 - TSCA subpoena OPPT?
 - PFAS council work on hazard Jeff; question 5
 - Expectation of disclosure question 11

3. What should states and others do with existing stock of Anvil 10+10?

To minimize risks to public health and the environment, EPA asked states with existing stock of the mosquito product distributed in HDPE containers to discontinue use and contact the manufacturer about their product exchange program.

4. Will affected products be placed under Stop Sale/Stop Use by EPA or State Lead Agencies?

EPA will respond to any additional PFAS supply-chain contamination issues on a case-by-case basis. For example, EPA worked with the mosquito product manufacturer to remove contaminated product from the supply chain.

Question: Does EPA have updates on this effort? Continuing to work on a case-by-case basis.
 No additional products have been identified as needing to be removed from the supply chain.
 Some companies voluntarily addressing concerns.

5. Will there be a similar response from EPA regarding Permanone 30-30?

EPA has received the letter and data from PEER on Permanone 30-30 and is reviewing as part of the agency's ongoing efforts to investigate PFAS contamination in pesticide products. EPA is committed to taking action to better understand and ultimately reduce the potential risks caused by these chemicals, including how to address PFAS contamination. EPA's actions to address these chemicals will be underpinned by science and will support the agency's efforts to develop effective regulation and provide

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improved public health protections for all Americans. EPA continues to work closely with the entities involved and their supply and distribution chains, mosquito control districts, the pesticide and packaging industry, federal partners, states, and tribes that may be affected to provide information and guidance on next steps. The agency is encouraging the pesticide industry to explore alternative packaging options. EPA understands the need to provide guidance to states, tribes, and other users as they prepare to purchase mosquito control products for 2021 and will provide more information as it continues its investigation.

Question: Does EPA have updates on this effort? Actively collaborating with Maryland to test
mosquito products; hopefully by the 20thh we'll be able to share our final report with Maryland.
Collaborating/coordinating on any public messaging around this. If other states need assistance,
let us know.

6. Are there continued considerations being given regarding State Lead Agency laboratories providing analytical support? If so, what are they?

EPA is actively communicating with state partners and their laboratories. For state laboratories that are interested in sharing samples, we encourage them to reach out to the BEAD/Ft. Meade lab to discuss laboratory equipment requirements.

- Questions: Does EPA and/or Ft. Meade lab have updates on this effort? What is the status of analytical method development and approval for PFAS residues in pesticides?
- Actively working to develop the method; some testing indicated a need for additional review using a more precise piece of equipment. That is being incorporated into the method. Hoping the method will be released (or ready for release) by the 20th.